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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/730,878	12/09/2003	Ruchika Singhal	1023-334US01	4796

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EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

NOTIFICATION DATE	DELIVERY MODE
01/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/730,878	SINGHAL ET AL.	
	Examiner	Art Unit	
	Michael Kahelin	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20071031*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over O'Hara (US 7,110,819, hereinafter "O'Hara").

6. In regards to claims 1, 3, 9, and 16, O'Hara discloses a device comprising at least two interconnected modules shown in at least two housings (the three modules shown as "206" in Figure 3); and an overmold comprising a first material to hold the modules (the two section of the housing/overmold 202 and 204) and a second material (252) that encapsulates each of the housings and comprising a lead connection module (244 and 246) embedded within the overmold and configured to accept a separable lead (col. 8, lines 24-30). Please note that the overmold is being interpreted as elements 202, 204, *and* 252.

7. Alternatively, although O'Hara *shows* the internal electrical componentry in modular form/separate housings in Figure 3, O'Hara does not explicitly *state* that these modules comprise individual housings. It is well known in the implantable stimulator arts to provide the various stimulator components such as the hybrid, battery, delivery capacitor, and communications circuitry in different housings to provide the predictable results of providing a desired form factor, containing liquid electrolytes, and avoiding electromagnetic interference. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify O'Hara's invention by providing the various stimulator components such as the hybrid, battery, delivery capacitor, and communications circuitry in different housings to provide the predictable results of providing a desired form factor, containing liquid electrolytes, and avoiding electromagnetic interference.

8. In regards to claim 2, because the elements of Figure 2 are in the modules (206), at least one module comprises electronic components.

9. In regards to claims 4, 10, and 17, the first material is non-elastomeric (col. 8, line 41).

10. In regards to claim 5, the connection module comprises a feed-through wire (248).

11. In regards to claim 6, the connection module comprises a mechanical lead securing mechanism (250).

12. In regards to claim 13 the connection module is embedded in the first material (at 242).

13. In regards to claim 14, the connection module is configured to receive an isodiametric lead, such as one having a diameter smaller than the bore hole (Fig. 4).

14. In regards to claim 15, the housings (left and right portions of 206 in Figure 3) are horizontally distributed and separately encapsulated by the overmold (202 and 204; they are encapsulated and separate).

15. In regards to claims 19 and 20, at least one of the two housings is hermetic (col. 8; lines 6 and 61) because they all lie within a hermetic seal.

16. Claims 7, 8, 11, 12, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hara. O'Hara discloses the essential features of the claimed invention except for tool-less lead securing, a thickness of 4-8mm, or an overmold comprising silicone elastomer. It is well known in the implantable device arts to provide tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements; implant thickness of 4-8mm to provide the predictable result of minimizing patient trauma; and overmolds, such as headers, comprising silicone elastomer to provide the predictable results of an inexpensive and biocompatible material that will provide a fluid-tight seal between leads and stimulators. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify O'Hara's invention by providing tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements; an implant thickness of 4-8mm to provide the predictable result of minimizing patient trauma; and an overmold comprising silicone elastomer to

provide the predictable results of an inexpensive and biocompatible material that will provide a fluid-tight seal between leads and stimulators.

17. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berrang et al. (US 6,358,281, hereinafter "Berrang").

18. In regards to claims 1, 9 and 16, Berrang discloses an implantable device comprising at least two interconnected modules (Fig. 2, elements 18 and 21, and the material directly surrounding elements 18 and 21, such as 24, 20, 25, and 23), each having a housing (24, 20, 25, and 23); and an overmold encapsulating each of the housings (gold and epoxy) and comprising a lead connection module (Fig. 1, intersection of 6 and 16). Please note an alternate interpretation wherein electronic module (21) is housed by support disc (33) and battery (18) inherently comprises its own housing because the battery is a lithium ion or nickel metal hydride-type (col. 12, line 55). These batteries contain liquid electrolytes necessitating a housing. In this interpretation, the epoxy and gold act as the overmold. Further, regarding claim 16, the epoxy acts as a frame because it is rigid. Berrang does not disclose that the lead is separable from the connection module. It is well known in the implantable stimulator arts to provide detachable leads to provide the predictable result of simplifying implantation by allowing the lead and device to be implanted or explanted separately. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's device by providing a detachable lead to

provide the predictable result of simplifying implantation by allowing the lead and device to be implanted or explanted separately.

19. In regards to claim 2, at least one module contains electronic components (21).

20. In regards to claims 3 and 13, the overmold comprises a first material and a second material (col. 12, line 8) and the lead connection module is embedded within the first material (because the lead conductors must pass through all coating materials (the epoxy, gold, palladium, titanium, and silicone of column 12, line 20) to reach the outside of the device, the lead connection module passes through the "first material"). Regardless of whether the lead is removably attached to the housing, the system comprises a lead connection module because the lead is connected to the internal electronics. This connection module comprises the conductors that connect 16 with the internal electronics 21. As the various housing and coating materials cover the conductors that connect the leads to the internal electronics (see Figure 2), these conductors are embedded, and a lead connection module.

21. In regards to claims 4, 10 and 17, the first material is non-elastomeric; depending on whether the epoxy resin, gold, or the other listed materials is considered to be "the first material".

22. In regards to claim 5, the device includes at least one feed-through wire (col. 11, line 3).

23. In regards to claim 8, the maximum thickness is between 4 and 8 millimeters (col. 10, line 9).

24. In regards to claims 11, 12 and 18, the second material is silicone (col. 12, line 25).

25. In regards to claim 15, the modules are horizontally distributed and separately encapsulated by the overmold (Fig. 2).

26. In regards to claims 19 and 20, the housings are hermetic via the overmold (col. 12, line 18).

27. In regards to claim 6, 7, and 14, Berrang discloses the essential features of the claimed invention except for an isodiametric lead or tool-less mechanical connection. It is well known in the art to provide implantable devices with isodiametric leads to allow the leads to be easily manufactured by extrusion processes and implanted with tubular catheters and to provide tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Berrang's invention by providing an isodiametric lead to provide the predictable result of allowing the lead to be easily manufactured by extrusion processes and implanted with a tubular catheter and to provide tool-less lead securing to provide the predictable result of a simple implantation that requires few implantation implements.

Response to Arguments

28. Applicant's arguments filed 10/31/2007 with respect to the Berrang reference have been fully considered but they are not persuasive. Applicant argued that

Berrang's disclosure describes the device as having a single housing comprising two sections. However, regardless of whether Berrang is referring to a single housing, Figure 2 clearly shows two housings, as the claim language requires. Applicant further argued that the epoxy does not house elements 2 and 3. Please note the new interpretation of "modules" above, necessitated by the presently amended claims. Applicant further argued that the gold layer forms a single housing for the two modules and is not an overmold. The current claim language does not prohibit the overmold from encapsulating each of the individual housings in a single housing.

Conclusion

29. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Meltzer (US 5,645,586) is one of many teachings of separately housing various stimulator components, and Stokes (US 5,324,312) is one of many teachings of tool-less lead connection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK
1/12/08

GEORGE R. EVANISKO
PRIMARY EXAMINER
1/14/8